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The Effect of Procedural Changes on the Rate of Clinical Alarms In the Intensive Care Unit

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**THE EFFECT OF PROCEDURAL CHANGES ON THE RATE OF CLINICAL
ALARMS IN THE INTENSIVE CARE UNIT**

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
Industrial Engineering

by
Puneeth Kalavagunta
August 2015

Accepted by:
Dr. David M. Neyens, Committee Chair
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ABSTRACT

Clinical alarms have become an indispensable part of medical environment, but issues related to alarm artifacts, false alarms, and alarm fatigue have been identified. A national online survey administered to hospitals stated healthcare workers determined that 81% of respondents agreed that alarms occur frequently, 77% agreed that excessive clinical alarms disrupt patient care, and 78% agreed that reduced trust in alarms cause caregivers to disable them (Korniewicz, Clark, & David, 2008). Studies have suggested that preparation of skin of the patient improves electrode-skin contact, thereby resulting in fewer artifacts (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000). Additionally, clinical studies have shown that the electrode-skin interface is frequently overlooked as a major source of artifact affecting many electro-physiologic recordings (Oster, 1998). The purpose of the thesis is to evaluate how the implementation of procedural changes, specifically implementing a patient's chest preparation procedure prior to electrode placement influences the rate of clinical alarms, (i.e., critical or warning cardiac alarms) in an intensive care unit (ICU).

Data from clinical alarms were collected from a regional hospital in South Carolina. The data contained the number of clinical alarms recorded with and without nurse administered chest preparation. Functional data analysis was used to evaluate if chest preparation procedure had a significant impact on the rate of clinical alarms produced over an 8-hour shift. The results suggest that there is no significant reduction in the alarm frequency after the implementation of nurse administered chest preparation.

However, a nominal decrease in the number of alarms per hour per patient and some preliminary trends were observed during the data analysis that warrants the need for future research in this direction.

DEDICATION

I would like to dedicate my thesis to all those who lost their lives or suffered due to preventable medication errors which are a result of the high frequency of alarms in an hospital ICU's.

ACKNOWLEDGEMENT

I would like to extend my sincere appreciation to my academic advisor, Dr. David Neyens for his continuous support and guidance throughout my masters' program. I would like to thank Dr. Rae Cho and Dr. Sara Riggs for serving on my thesis committee and providing recommendations and comments to the advancement and completion of my study. Finally, I would to thank all my friends and family throughout my graduate program.

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Chapter One

INTRODUCTION

In order to effectively monitor the health status of patients admitted to an intensive care unit (ICU), healthcare professionals often need to cognitively process large quantities of highly heterogeneous information, including a medical history, X-rays, ultrasound scans, laboratory analyses and data from examinations. (Otero, Félix, Barro, & Palacios, 2009). Among this information, the majority of the workload overload results from the monitoring of physiological variables such as electrocardiogram, blood pressure, heart rate, and breathing rate, as these variables vary over time and require continuous attention in order to successfully predict and avoid life-threatening situation for the patient (Otero et al., 2009).

Intensive care units are equipped with sophisticated medical equipment to assist healthcare providers in handling the overwhelming information available from multiple physiological variables. Although the medical devices in ICU's have incorporated a number of improvements over the last few decades, including larger screens, storage capability of recorded signals and alarm triggers that can be controlled, the capability to monitor multiple physiological variables, the primary method of identifying initial indications of a deterioration in a patient's health is through the use of threshold alarms (Otero et al., 2009). Threshold alarms are triggered each time the value of a variable leaves a pre-established range (Otero, Félix, Palacios, Pérez-Gandía, & Sorzano, 2007).

Clinical alarms have become an indispensable part of medical environment, but issues related to alarm artifacts, false alarms, and alarm fatigue have been identified

(Cvach, 2012; Tsien, Kohane, & McIntosh, 2000). False alarms are defined specifically as those coinciding with a clearly observed, unrelated cause (Wiklund, Hok, Stahl, & Jordeby-Jonsson, 1994). Artifact alarms are a result of human manipulation and a major source of alarms that are not clinically relevant (Siebig, Kuhls, Imhoff, Langgartner, et al., 2010). However, another study generalizes artifact alarms as clinically irrelevant alarms which are caused by some factor other than what is being monitored, such as light sources, equipment issues, or other types of interference (The Joint Commission, 2013). Alarm fatigue is considered as the failure to recognize and respond to true alarms that require clinical intervention as a result of high occurrence of alarms (Welch, 2011).

Audible alarms can produce unintended consequences that undermine quality and patient safety when they occur at a high frequency (Harris, Manavizadeh, McPherson, & Smith, 2011). If the clinical alarms are more often false than clinically relevant, it is possible that a work culture emerges whereas hospital staff may delay response to alarms, especially when occupied in other patient care activities, and critical alarms can be missed (Cvach, 2012; Graham & Cvach, 2010; Welch, 2009). This phenomenon of medical providers becoming desensitized to the constant noise being emitted by the monitors that they fail to notice the alarms or react in a timely manner is described as “clinical alarm fatigue” (Whalen et al., 2013).

Problems contributing to clinical alarm fatigue can be broadly classified as: 1) nonactionable alarms, 2) false alarms, and 3) lack of education, policies, or procedures to guide practice and reduce alarms (Purbaugh, 2014). The plausible interventions recommended for nonactionable alarms are: 1) monitor only those patients with clinical

indications for monitoring (Hweidi, 2007), 2) modify alarm parameters on ECG monitors (Graham & Cvach, 2010; Welch, 2011) and 3) customize and delay threshold settings for pulse oximetry monitoring (Hweidi, 2007). Interventions recommended for false alarms are: 1) Perform proper skin preparation for ECG electrodes (Hweidi, 2007; Sendelbach, & Jespen, 2013), 2) change ECG electrodes daily (Cvach, Biggs, Rothwell, & Charles-Hudson, 2012) and 3) pause alarms during patient care (Hweidi, 2007). The interventions recommended for lack of education, policies or procedures are: 1) Standardize the monitoring process throughout clinical areas (Block, Rouse, Hakala, & Thompson, 2000), 2) provide education about monitoring devices and how to modify parameters (Graham & Cvach, 2010), and 3) establish inter-professional teams to address alarm issues (Graham & Cvach, 2010).

In addition to contributing to alarm fatigue, high frequency of alarms negatively impact patients who hear alarms and are unaware of their source by increasing their anxiety level (Whalen et al., 2013). Patient survey questions regarding noise level in patient rooms consistently receive the lowest ratings, with noise negatively impacting the patient's overall perception of the quality of the hospital experience (Mazer, 2000; Montague, Blietz, & Kachur, 2009). In fact, noise in hospitals has been shown to reduce a patient's ability to improve their health (Call, 2007). For example, exposure to sudden, unexpected noise raises patient heart rates and has been proven to have a negative influence on patient recovery times (Maschke, Rupp, & Hecht, 2000). A team of European researchers, in a study found that chronic noise increased risk of heart attacks by 50 percent for men and 75 percent for women (Willich, Wegscheider, Stallmann, &

Keil, 2006). Data gathered from the last four decades indicate a trend of increasing noise levels during daytime and nighttime hours (Busch-Vishniac et al., 2005). Therefore, it is essential to mitigate the noise levels in ICU's not only to help improve patient care, but also to help improve patients' overall hospital experience, and thus health.

Clinical equipment are increasingly fitted with alarms to notify healthcare professionals of the sudden changes in their physiology that may be detrimental to patient being monitored. It is estimated that between 85% and 99% of alarm signals do not warrant clinical intervention (Purbaugh, 2014). The problem with increasing dependence on physiological monitoring technology in hospitals and especially critical care units is that the sheer number of alarms can overwhelm medical staff (Purbaugh, 2014). In fact, studies suggest that with the advances in electronic monitoring devices, the data available exceeds the cognitive capabilities of the medical staff resulting in counter-productive situations (Bellazzi et al., 1996; Milios & Nawab, 1989; A. Otero et al., 2007; Shahar & Musen, 1996). The key contributing factors are increasing rates of false alarms overloading human auditory channel and poor equipment design (Edworthy & Hellier, 2005).

Alarms originate from a plethora of medical devices in an ICU. In this process, false alarms are triggered by many devices and in some cases false alarms represent over 90% of all alarms (Schoenberg, Sands, & Safran, 1999). As a result, healthcare professionals were affected by alarm desensitization, mistrust, and lack of caregiver response due to alarm fatigue. This has also resulted in nurses and physicians silencing notorious devices or setting alarm limits that are unlikely to be exceeded which may

compromise patient safety (Schoenberg et al., 1999). As a result, it is critical to reduce the rate of alarms in an ICU via reducing or eliminating false alarms so that the cognitive workload of healthcare professionals is minimized and patient safety is not compromised (Deaton & Parasuraman, 1993).

A national online survey administered to hospitals stated healthcare workers found that 81% of respondents believed that alarms occur frequently, 77% believed that excessive clinical alarms disrupt patient care, and 78% believed that reduced trust in alarms cause caregivers to disable them (Korniewicz et al., 2008). Lawless (1994) recorded the type and number of alarms triggered during a 7-day period in a pediatric ICU. The alarms were recorded as false alarms, significant (resulted in change in therapy), or induced (by staff manipulations; not significant). Of the total 2,176 alarms triggered, 68% were false, 26.5% were induced and only 5.5% were found to be significant (Lawless, 1994). In another study on cardiovascular alarms it was found that 68% of the alarms were caused by manipulation and only 15% of the alarms were considered clinically relevant (Siebig, Kuhls, Imhoff, Gather, et al., 2010). A research study was conducted in medical intensive care unit of a university hospital to report rate of cardiovascular alarms and their clinical validity (Siebig, Kuhls, Imhoff, Gather, et al., 2010). The study conducted over a span of 17 months found that six alarms were triggered per hour on average and only 15% of these alarms were considered clinically relevant. Another study conducted in a 79-bed community hospital found that the average number of alarms per patient per hour was 8.4 alarms (Gross, Dahl, & Nielsen, 2011).

The same study suggested that alarm load could be reduced by more than 50% by setting appropriate control limits appropriate to the population.

Multiple approaches have been identified to tackle the high frequency of alarms in ICUs. Some of the studies have suggested making alarms sounds specific to medical devices as healthcare professionals complained it was difficult to identify which device was alarming due lack of standardization of alarms (Block, Nuutinen, & Ballast, 1999). In this regard, another study proposed a new set of alarm sounds which satisfy existing standards and encode source information to help prevent confusion which would otherwise result in different manufacturers choosing different melodies for their equipment (Block et al., 2000). Studies have also suggested the use of improved signal extraction algorithms to reduce the number of false alarms triggered (Borowski, Siebig, Wrede, & Imhoff, 2011; Imhoff & Kuhls, 2006). Borowski et al., (2011) validated the use of online signal filters whose performance criteria were sensitivity and the proportion of false alarms suppressed. Several statistical approaches are being investigated for use in alarm systems such as: 1) improved signal detection, 2) artifact filters, 3) statistical process control, 4) time-series analysis techniques and 5) dynamic linear models (Imhoff & Kuhls, 2006).

Another approach to addressing the high rate of alarms may be procedural changes that help in reducing false alarms. For example, a study recommended changes in sensor placement procedures to reduce false alarms in surface electromyography (SEMG) sensors (Hermens et al., 2000). The study proposed that preparation of patient's skin could improve electrode-skin contact, thereby resulting in fewer artifacts.

Additionally, clinical surveys have shown that the electrode-skin interface is frequently overlooked as a major source of artifact affecting many electro-physiologic recordings (Oster, 1998). It was also found that proper skin preparation can help lower skin impedance which in turn results in reduced artifact alarms and increased alarm effectiveness (Oster, 1998). Skin impedance is described as the opposition of the skin surface to the passage of electrical signals. Factors such as age, sun exposure, skin lotions, relative humidity, and ambient temperature can influence skin impedance (Oster, 1998). Standard skin preparation techniques are shaving, rubbing/abrasion, cleaning of the skin, or a combination of these techniques. Also, performing proper skin preparation for ECG electrodes was found to be one of the plausible interventions in order to tackle the issue of false alarms (Hweidi, 2007; Sendelbach, S., & Jespen, 2013).

Objective

Given the literature and the opportunities to reduce the rate of false alarms in an ICU, the purpose of the thesis is to evaluate how the implementation of procedural changes, specifically patient's chest preparation prior to electrode placement influences the rate of clinical alarms, (i.e., critical or warning cardiac alarms) in an intensive care unit (ICU). This approach has been recommended in the literature but few studies document evidence of its effectiveness both immediately and over the duration of time. This study seeks to address this gap in the literature.

Chapter Two METHODOLOGY

2.1 Specific objectives

The specific objectives of this thesis are to evaluate:

1. How the number of alarms triggered differs for patients who had chest preparation administered compared to those without chest preparation.
2. If the effect due to the implementation of procedural change (if significant) may degrade (or change) over time with deterioration of sensor-skin contact.

2.2 Data Sources

Clinical alarms data was collected from a regional hospital in South Carolina. As part of the process improvement study, the hospital implemented nurse administered patient chest preparation prior to electrode placement. The procedure included washing a patient's chest every morning before 9 am and placing new electrodes on the patient. The same procedure was completed every day by the same nurse for over 49 patient days. The number of alarms triggered between 9 am and 5 pm was documented automatically through the data logs for the monitors of four physiological variables 1) heart rate, 2) respiration rate, 3) oxygen saturation, and 4) blood pressure. An alarm is triggered when at least one of these variables measured indicates deteriorating patient's health.

Similar data was recorded for 48 patient days prior to the implementation of chest preparation. Thus, data contains the number of clinical alarms recorded with and without nurse administered chest preparation. The data collected does not contain any patient's individual information.

The alarms triggered were classified into yellow and red alarms via the automated data logging system. The yellow alarms represent moderately important alarms, whereas red alarms represent critical alarms that are highly important. Both the alarms are combined and analyzed as the focus of this study is on the frequency of alarms rather than their importance as all alarms required the hospital staff to respond to the equipment and take to necessary actions.

2.3 Data Reduction

From pre-procedural change data, two patient's data were excluded as they appeared to be duplicates, which may have been an issue with data extraction from the system. In addition, 18 patients were excluded as they failed to have any alarms during the 8-hour observation period or for having abnormally high alarms in at least period of the study. A research study was conducted in medical intensive care unit of a university hospital to report rate of cardiovascular alarms and their clinical validity (Siebig, Kuhls, Imhoff, Gather, et al., 2010). The study conducted over a span of 17 months found that six alarms were triggered per hour on an average and only 15% of these alarms were considered clinically relevant. Another study conducted in a 79-bed community hospital found that the average number of alarms per patient per hour is 8.4 alarms (Gross et al., 2011). In our study, any patients who trigger more than 25 alarms in one hour were excluded from the data analysis. Several data were excluded from the post-procedural change set. Specifically nine patients were excluded for triggering abnormally high alarms or failing to have any alarms during the 8-hour observation

period. Also, one patient was excluded for having incomplete data of the number of alarms recorded (i.e., there were missing values in the alarm data).

After data reduction, 28 patient-day observations are included in the pre-procedural change set and 37 patient-day observations are included in post-procedural change set.

2.4 Functional data analysis (FDA)

Functional data is a branch of statistics that has a defining quality of often providing information about smooth curves (Ramsay & Silverman, 2005). Functional data are generated from underlying continuous functions. Each observation consists of discrete measurements taken at a certain time or location as in this study. But, these data points are assumed to arise from a smooth function in FDA. So, the discrete data collected is made to undergo smoothing through many possible transformation techniques. The smoothness or regularity will be a key aspect of the data analysis and help in identifying interesting trends over time. FDA is useful in understanding deterioration of skin preparation over time in the effect deterioration. Functional data analysis does not require the data to be normally distributed. This is helpful as the data collected for this study does not adhere to normal distribution.

Interest is in functions as such rather than the individual measurements and therefore FDA differs from traditional multivariate analysis in both conceptual framework and statistical tools used for analysis (Sørensen, Goldsmith, & Sangalli, 2013). For example, the medical questions to be answered could be ‘How is the function x associated with the severity of a disease and with survival from the disease?’ or ‘Which

subjects exhibit similar patterns of a tumor, or how do we estimate an intrinsic scale of each individual?'; Functional data analysis enables us to answer such questions regarding regression and prediction, clustering and variations in the time/space direction (Sørensen et al., 2013). FDA has applications of finance as well with typical examples being implied volatility markets, yield curves or risk-neutral densities (Benko, 2007).

In functional data analysis, we use a set of functional building blocks called basis functions which are combined linearly. The most popular basis systems are: 1) B-splines and 2) Fourier series. Fourier series are used for periodic or near periodic data such as weather data, some kinds of economic data with periodic motions. However, when the data is not periodic as in this study, splines are used. Also, splines are much better at fitting highly curvy data compared to Fourier series which are not as effective at capturing sharp changes. A scalar covariate model is used for data analysis which is defined as:

$$y_i(t) = \beta_0(t) + \beta_1(t)x_i(t) + \varepsilon_i(t)$$

Where, y_i = number of alarms in time t .

β_0 = global average number of alarms in time t .

β_1 = parameter estimate of washing for $x_i(t)$.

$x_i(t) = 0$ for pre-procedural change and 1 for post procedural change across time t .

Chapter Three RESULTS

Initially, 97 patient day observations were collected in which 48 patient days were observed for pre-implementation of chest preparation and 49 patient days were observed for post-implementation of chest preparation. Each patient day observation consists of number of alarms documented hourly over the 8-hour observation period. After data reduction, 65 patient day observations remained which included 28 patients pre- and 37 patients post-chest preparation implementation. Figure 3.1 (a) represents 28 patient day observations from pre-implementation of chest washing. Whereas, Figure 3.1 (b) represents 37 patient day observations from post-implementation of chest washing. Line-charts plotted with these patient day observations is as follows:

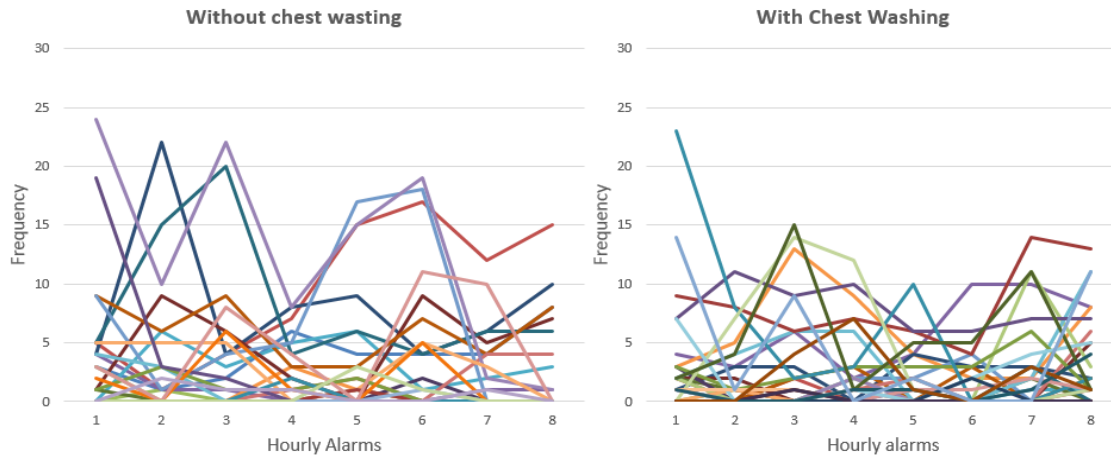


Figure 3.1: (a) Pre-chest preparation patients' data, (b) Post-chest preparation patients' data

The initially gathered contained discrete number of alarms triggered during the 8-hour observation period. This finite data is smoothed so that they can be evaluated at infinite number of points using a continuous function (Ramsay, Hooker, & Graves,

2009). The 65 patient day observations obtained after data reduction were smoothed via 7 b-spline functions. The resulting data appear in Figure 3.2.

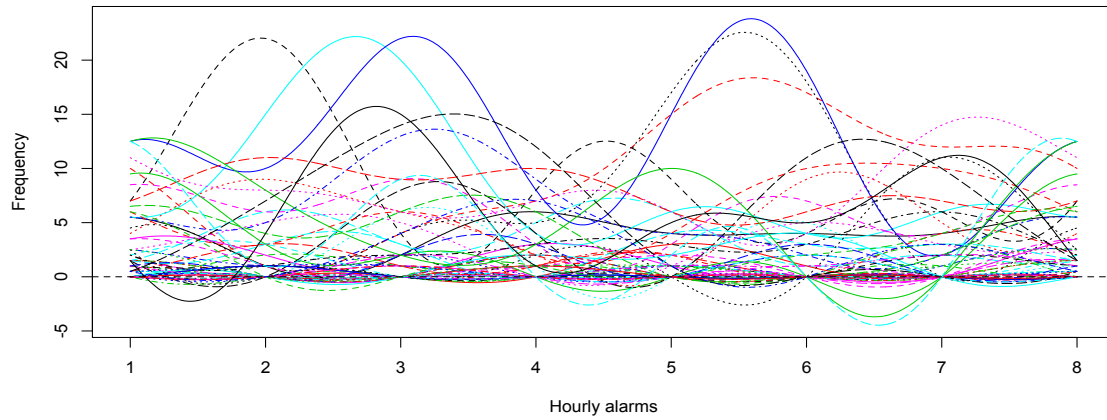


Figure 3.2: Patient day observations plotted after data reduction and smoothing

In Figure 3.3, the x-axis represents the hourly alarms over the 8-hour observation period (9am – 5pm). The y-axis represents the number of clinical alarms triggered. When the data is plotted separately for the pre-procedural change (without chest preparation) and with chest preparation, it would appear as follows:

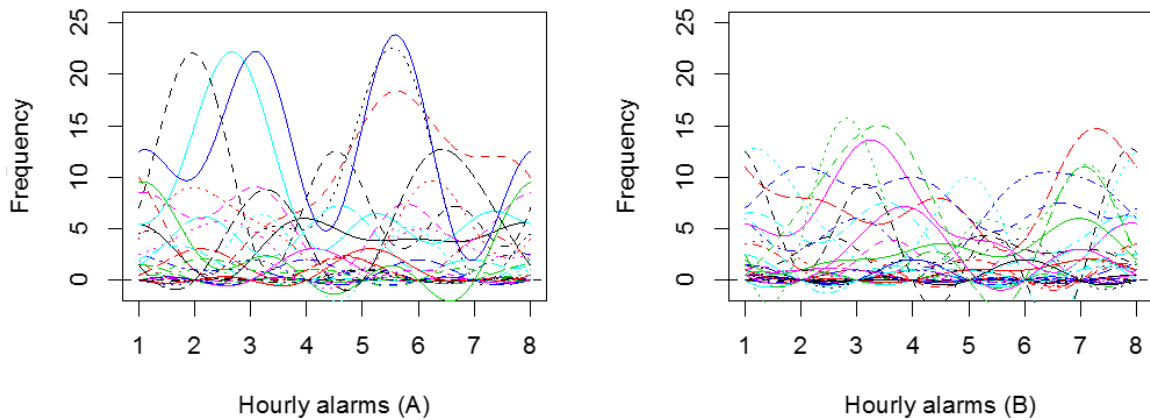


Figure 3.3: Smoothed data for pre-procedural (A) and post-procedural (B) procedural change respectively.

The results of the FDA can be seen in Figure 3.4. Global mean alarm frequency can be seen varying between 3.15 alarms per hour and 2.85 alarms per hour. In Figure 3.4 (b), the alarm frequency during post-chest preparation implementation reduces by almost one alarm in the first three hours (8-11 am) of the observation period. The alarm reduction rate increases relatively to 1.25 alarms in the next three hours (11 am - 2 pm). In the last two hours (2 pm – 4 pm), the reduction in alarm frequency reduces and falls back to 0.95 alarms by the end of the observation period (4 pm). When a 95 percent confidence interval is added to Figure 3.4, it would appear as follows:

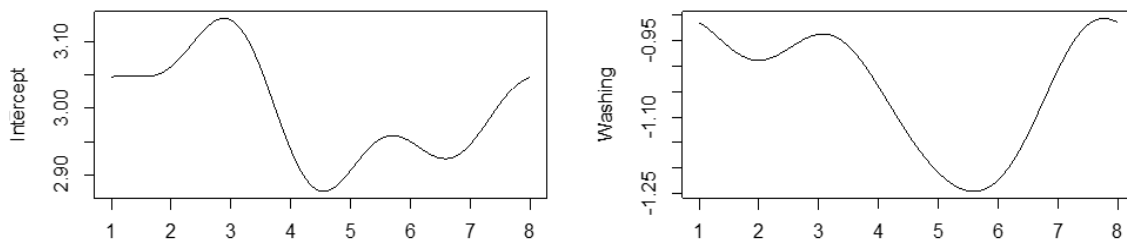


Figure 3.4: (a) The mean trend for pre and post procedural change data, (b) The difference between the number of alarms between post and pre procedural change data.

Figure 3.5 is derived from Figure 3.4 after applying 95 percent confidence intervals. The selection of confidence level for an interval determines the probability that the confidence interval produced will contain the true parameter value. Figure 3.5 (a) shows that the mean alarm frequency is varying between two and four. Figure 3.5 (b) shows that the 95 percent confidence interval limits for difference in number of alarms between pre- and post-procedural change implementation are -2.5 and 0.5 alarms per hour. As the confidence interval includes zero, the difference in the number of alarms is not statistically significant. But, it can be that on an average, approximately one alarm is

less for every hour of the observation period. It is also interesting how Figure 3.4 shows that the effect of the procedural change is most effective during after lunch hours (1pm-2pm).

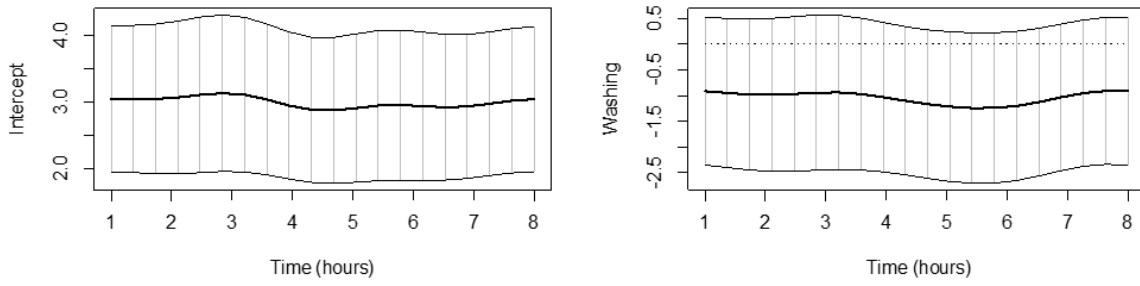


Figure 3.5: With 95 percent confidence intervals, (a) The mean trend for pre and post procedural change data, (b) The difference between the number of alarms of pre- and post-procedural change data.

Chapter Four

DISCUSSION AND CONCLUSIONS

Figure 3.3 displays a comparison of number of alarms between pre-procedural change data (without chest preparation) and post-procedural change data (with chest preparation) after smoothing data. The smoothing of data is useful in converting the discrete data points into a continuous function necessary for functional data analysis. A considerable difference in the number of alarms can be seen between the plots. The overall number of alarms triggered in the plot representing patients who are administered chest preparation appears to be less than the number of alarms triggered in the plot representing patients who are not administered chest preparation.

After the application of functional data analysis, we obtain the mean trends of clinical alarms documented as a continuous function of time. Figure 3.4 (a) displays how the grand mean of the clinical alarms varied as a function of the 8-hour observation period of the study. Figure 3.4 (b) represents the difference between the number of alarms documented in post- and pre-chest preparation observations. This plot does not demonstrate any significant difference after the implementation of the procedural change. Since the plot established a confidence interval that includes zero, a significant reduction in the number of alarms was not detected.

Some interesting minor trends can be analyzed in Figure 3.4. Figure 3.4 (b) describes how reduction in rate of alarms is almost stable with minor variations in first three hours (8am–11 am), gradually increases in the next three hours (11am–2 pm), and falls back to initial alarm reduction rate in the last two hours (2pm–4pm) of the 8-hour

observation period. The effect of washing is maximum during the fifth observation hour (1pm–2 pm). This time period is considered as after-lunch period by the hospital nurses. This is an interesting trend found in the FDA results that needs further research to analyze it in depth.

4.1 Limitations

The study encompasses several limitations. The patients observed from pre- and post-procedural change implementation were not random as it was not a controlled experiment. The observation period is during daytime and only for a period of 8-hours (8am–4pm). A 24-hour observation period might give more insights on the effectiveness of chest preparation. During the data analysis, yellow (moderate risk) and red alarms (high risk) were combined as the focus of the study was to analyze variations in number of alarms and not the severity of the alarms. Analysis of the data separately based on the type of alarms might have resulted in different inferences that this study failed to identify.

Patients with preliminary diagnosis such as alcohol withdrawal tend to trigger more number of alarms on an average compared to other patients. This could be because the spectrum of alcohol withdrawal symptoms ranges from minor symptoms such as insomnia and tremulousness to severe complications such as withdrawal seizures and delirium tremens (Bayard, McIntyre, Hill, & Woodside, 2004). The data obtained for this study is collected after de-identifying any personal information of the patients including their preliminary diagnosis. If the preliminary diagnosis of the patients was known, it would help in comparing patients with similar kinds of diagnosis to obtain better results.

4.2 Conclusions

Functional data analysis is a relatively new analysis approach that is increasing finding numerous applications in healthcare (Sørensen et al., 2013). FDA could be applied in multiple healthcare departments and as mentioned earlier could be useful in probing medical questions such as ‘How is the function x associated with the severity of a disease and with survival from the disease?’ or ‘Which subjects exhibit similar patterns of a tumor, or how do we estimate an intrinsic scale of each individual?’ (Sørensen et al., 2013). This can make FDA a useful tool in reducing alarm fatigue by identifying the related factors at root.

The study shows some preliminary trends in the frequency of alarms triggered after the nurse administered chest preparation. In this study, chest preparation is conducted with soap and water. However, other chest preparation techniques include washing chest with alcohol, chest rubbing/abrasion and chest shaving. These other techniques may have more effective outcomes than the procedural change adopted in this study. Further research is needed in this regard to establish the effectiveness of these procedural changes in curbing the high frequency of alarms in ICUs. Also, the effect of chest preparation was found to be most effective during after lunch hours. But, it is not clear why this effect has been observed. This is a major opportunity for future research to investigate further.

FDA has the potential to translate into other domains. Some of the examples could be finance, weather forecast or manufacturing sector. FDA can also be used in handwriting analysis (Ramsay et al., 2009). Within healthcare, FDA could be used in

other kinds of clinical assessment studies. It can be used in the design of healthcare processes. For example, application of FDA in alarm fatigue alarm and alarm frequency studies could help in the design of effective specification limits of the monitoring devices in hospitals.

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